High Frequency Spinal Cord Stimulation at 10 kHz for the Treatment of Focal, Chronic, Post-Surgical Neuropathic Pain

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Introduction

Chronic post-surgical pain (CPSP) is one of the most common and serious complications after surgery. A recent multicenter observational study reported a 12-month incidence of 11.8% moderate CPSP and 2.2% severe CPSP (i.e. numeric rating scale [NRS] ≥3 and ≥6, on a scale from 0 to 10, respectively). The focal nature of the pain may warrant targeting a neural structure like dorsal root ganglion (DRG) to elicit pain relief. However, early pre-clinical evidence from high frequency SCS (HF-SCS) at 10 kHz demonstrated an inhibitory effect on projection interneurons in the superficial layers of dorsal horn. Thus, we hypothesized that HF-SCS at 10 kHz may provide effective pain relief in focal CPSP conditions.

Methods

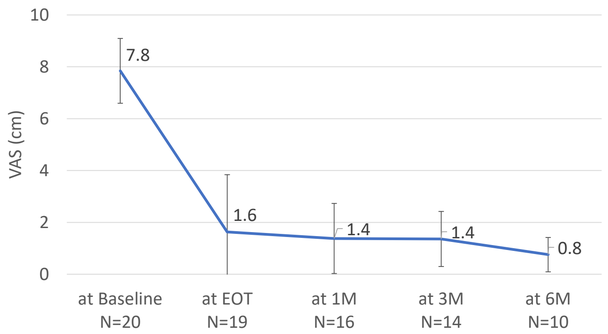
Subjects with focal chronic neuropathic pain of ≥5 out of 10 cm visual analog scale (VAS) score of the trunk or limb from CPSP were enrolled in this single center prospective study. After approval from ethics committee, subjects who completed a written informed consent underwent a trial stimulation. Two epidural leads were implanted spanning the appropriate vertebral bodies determined by the location of pain. Those with a successful trial (≥50% pain reduction) received a permanent Senza system (Nevro Corp., Redwood City, CA) and were followed-up at regular intervals for 12 months to collect safety and effectiveness data. Interim six month results are presented as mean ± standard deviation in the permanent implant population.

Results: Trial Results, Pain Scores, Disability and Pain Interference

Results: Trial Success

- Subjects trialed: 19
- Trial success: 17/19 (89,5%)
- Pain Location:
  - Lower extremity: 14
  - Trunk: 3
  - Upper extremity: 2

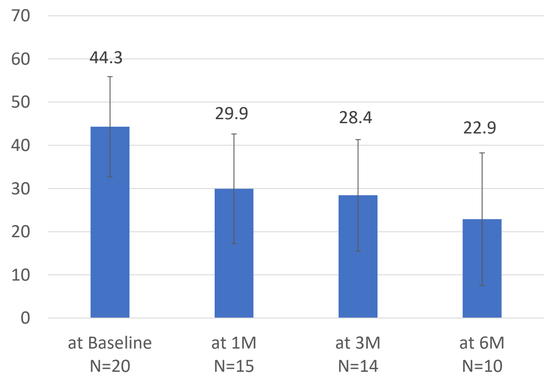
Results: Pain Scores



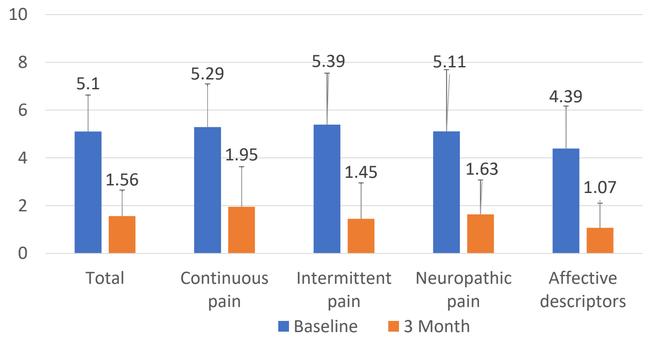
Responder rates @ 1, 3 & 6 mos: 89, 94 & 93%

Results: Pain Disability Index

- Disability assessed by PDI (Range 0-70)
- Lower index score = less disability
- Minimal important clinical difference (MCID): 8,5-9,5
- At 3 and 6 months: 15,9 and 21,4 point reduction in PDI



Results: Pain Interference (SF-MPQ2)



- Significant improvements were reported in all domains including affective component.

Results: Safety

AEs: 5 (Study related: 1)	
Subjects experiencing AEs	6
Study related serious AEs	0
Study related non-serious AEs	1 (Procedure related)

AEs by Severity		AEs by Outcome	
Mild	4	Death	0
Moderate	1	Resolved	5
Severe	0	Ongoing	0

A total of 5 AEs were reported in 6 subjects. Only one AE was procedure/study/device/stimulation related (infection of the percutaneous trial leads). All adverse events (AEs) were resolved.

Conclusions

Early results from this single-center, prospective study using HF-SCS at 10 kHz to treat chronic focal post-surgical pain suggest that a midline epidural, anatomically guided lead placement may offer an effective treatment to focal pain without the need for targeted stimulation. The results from this study are similar to that of a multicenter, prospective study from the United States.

References

[1]Fletcher D et al (2015), Eur J Anaesthesiol
[2]Scowcroft J et al. (2018) NANS, Las Vegas
[3]Soer et al (2012) Spine